



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

d16406

PHILADELPHIA DISTRICT

Warning Letter

900 U.S. Courthouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-297-4390

December 16, 1996

97-PHI-08

CERTIFIED MAIL
RETURN RECEIPT REQUIRED

Arthur Mellinger
359 May Post Office Road
Strasburg, Pennsylvania 17579

Dear Mr. Mellinger:

GEN.	SPEC.
RELEASE	
F#	DATE 12/18/96
Reviewed by: <i>[Signature]</i>	

On October 25, 1996, your dairy farm located on 359 May Post Office Road in Strasburg, Pennsylvania was visited by Food and Drug Administration (FDA) investigator Gerald W. Kopp in response to a United States Department of Agriculture (USDA) report regarding an illegal drug residue in a cow you offered for sale and slaughter for human food. Our inspection confirmed that you offered a cow for sale for slaughter for human food in February 1996 in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about May 22, 1996, you offered a cow, back tag "2247" for slaughter as human food at [REDACTED]

USDA analysis of tissue samples collected from the animal identified the presence of 0.34 ppm penicillin in the kidney tissue. The tolerance for penicillin in edible portions of bovine tissue is 0.05 ppm. The presence of penicillin in edible portions of bovine tissue at a level above the set tolerance causes the food to be adulterated under Section 402(a)(2)(D) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the

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foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused or participated in causing the adulteration of an animal that was offered for sale to a slaughterhouse that ships beef in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reasons for the delay and the timeframe in which correction will be achieved. Please include copies of any available documentation demonstrating that correction has been accomplished.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Very Truly Yours,



Diana J. Kolaitis
District Director
Philadelphia District

jci

cc: Dr. Max A. Van Buskirk, Director
PA State Bureau of Animal Industry
Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17120

cc: Dr. F.R. Rellosa
USDA Northeast Regional Office
701 Market Street
2B South
Mellon Independence Center
Philadelphia, PA 19102-1516